REMARKS

Information Disclosure Statement

A new IDS is filed herewith or will be filed in the near future citing the US equivalent of reference B10, which is US 7,368,578, and providing a copy of reference C13.

Rejections Under 35 U.S.C §112, first paragraph

Claims 11, 13-16 and 18 are rejected under 35 U.S.C §112, first paragraph, for not being enabling for the treatment or prevention of sleeping disorders and schizophrenia and prevention of menstrual syndrome.

Claim 14 is directed to a pharmaceutical composition, and claim 15 is directed to a process of preparation. The rejection thereof is not justified by the reasons/allegations provided, which concern methods of use.

Methods of prevention have been removed from the claims. Support for the amendments to the method claims can be found, e.g., at the bottom of page 4 of the application.

The Office Action cites Roth et al. on page 4 of the Office Action and admits that this reference teaches a nexus between 5-$HT_{2A/2C}$ antagonism, but alleges that the disclosure thereof suggests that future research is needed to determine if the 5-$HT_{2A/2C}$ receptor is a viable *in vivo* target.

The exact language referred to in Roth et al. is quite different than the alleged disclosure of Roth et al., which is the primary evidence offered by the Office Action in rejecting the claims.

On page 690, in section 3.3 this reference does not teach that "5-$HT_{2A/2C}$ antagonism may be linked to treatment of sleeping disorders," as alleged. Instead, this reference teaches that "there is abundant evidence to suggest that 5-$HT_{2A/2C}$ antagonism may improve sleep patterns in normal and depressed individuals." Internal citations omitted. Thus, Roth clearly cites "abundant evidence" supporting a nexus between sleep disorders and 5-$HT_{2A/2C}$ antagonism.

In the conclusion section this reference does not teach that "the 5-$HT_{2A/2C}$ receptor may be a potential avenue of treatment for a large number of common diseases including

depression, anxiety, schizophrenia, OCD, and obesity," as alleged. Instead, this reference teaches that "it is now clear that targeting the 5-HT_2 family of receptors is likely to continue to be fruitful for drug development strategies since drugs potentially useful for a large number of common diseases including depression, anxiety, schizophrenia, OCD and obesity (and its related illnesses CAD and NIDD) are possible." Thus, what Roth et al. teaches is a nexus between 5-HT_2 and various diseases, and it is provided by the use of highly positive terms such as "it is clear" and "continue to be fruitful" and "are possible."

And even if the allegations were correct that this reference may suggest that more research may be needed to evaluate the *in vivo* aspects, such is not a proper reason under US patent law for the maintenance of this rejection.

See, the holding of the Federal Circuit in *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1441 (Fed. Cir. 1995), in the context of an enablement rejection, and the statement in the option as reproduced below:

> usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful can be well before it is ready to be administered to humans. If the courts were to require Phase II testing in order to prove utility for pharmaceutical inventions, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.

Accordingly, the reconsideration of the rejection is respectfully and courteously requested.

Rejections Under 35 U.S.C §112, second paragraph

The definition of Het is amended rendering this rejection moot. For support, see, e.g., pages 11-16 of the specification.

The definitions of R^3 and R^6, which contained Het are also amended in view of the disclosure on page 10. See also original claims 2 and 5.

Rejections Under 35 U.S.C §102 and §103

The amendments to the claims, e.g., see the amendments to R^1, render the section 102 rejections moot over the two citations by Rainer, each disclosing the same compound 3-Methyl-5-phenyl-1-(p-biphenylyl)-pyrazol-4-acetic acid.

WO 03/031435 does not anticipate the claims and also does not render obvious any of the claims. The Office Action appears to have overlooked that the location of X, which is always N in the allegedly conflicting compounds of said reference, are not in the same position as the group X of the present claims. Because this difference was not ascertained and/or accounted for when alleging obviousness, the rejection is improper.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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